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NOTICE OF ALLOWANCE AND FEE(S) DUE

22249 7590 03/22/2004

LYON & LYON LLP
633 WEST FIFTH STREET
SUITE 4700
LOS ANGELES, CA 90071

EXAMINER	
BAUTISTA, XIOMARA L	
ART UNIT	PAPER NUMBER
2173	3

DATE MAILED: 03/22/2004

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,439	03/30/2001	Michael R. Dunlavey	263/015	5695

TITLE OF INVENTION: UNIT TRACKING AND NOTIFICATION IN A GRAPHICAL DRUG MODEL EDITOR

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	$665	$0	$665	06/22/2004

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:
A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status is changed, pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above and notify the United States Patent and Trademark Office of the change in status, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check the box below and enclose the PUBLICATION FEE and 1/2 the ISSUE FEE shown above.

❑ Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (Rev. 11/03) Approved for use through 04/30/2004.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 4 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Legibly mark-up with any corrections or use Block 1)

22249 7590 03/22/2004

LYON & LYON LLP
633 WEST FIFTH STREET
SUITE 4700
LOS ANGELES, CA 90071

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO, on the date indicated below.

(Depositor's name)

(Signature)

(Date)

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nonprovisional	YES	$665	$0	$665	06/22/2004

EXAMINER	ART UNIT	CLASS-SUBCLASS
BAUTISTA, XIOMARA L	2173	345-763000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent); ❑ individual ❑ corporation or other private group entity ❑ government

4a. The following fee(s) are enclosed:

❑ Issue Fee

❑ Publication Fee

❑ Advance Order - # of Copies _____

4b. Payment of Fee(s):

❑ A check in the amount of the fee(s) is enclosed.

❑ Payment by credit card. Form PTO-2038 is attached.

❑ The Director is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

Director for Patents is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.

(Authorized Signature) (Date)

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Alexandria, Virginia 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMIT THIS FORM WITH FEE(S)

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DATE MAILED: 03/22/2004

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 662 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 662 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (703) 305-1383. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

PTOL-85 (Rev. 11/03) Approved for use through 04/30/2004.

Notice of Allowability	Application No. 09/823,439	Applicant(s) MICHAEL R. DUNLAVEY	
	Examiner X L Bautista	Art Unit 2173	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *communications filed on 3/30/01*.

2. ☒ The allowed claim(s) is/are *1-20*.

3. ☒ The drawings filed on *30 March 2001* are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 2
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

Reasons for Allowance

1. Claims 1-20 are allowed.

2. The following is an examiner's statement of reasons for allowance:

Independent claims 1, 9, and 17 have been carefully considered. Prior art of record fails to teach the combination of claimed elements including a method and system for maintaining consistent unit relationships in a pharmacological computational model editor having a graphical user interface (GUI) that has a plurality of objects representing pharmacokinetic elements and pharmacodynamic elements; receiving instructions via the GUI for connection of at least two objects; displaying the connected objects having an input and an output; receiving units-specifying data for the input and output; converting the connected objects and the units-specifying data into an internal format corresponding to the pharmacokinetic and pharmacodynamic elements represented by the connected objects, wherein the converting step occurs substantially coincident with the object displaying step, the internal format comprising statements having terms, and the terms having an associated multidimensional unit type data for each statement; identifying inconsistent units in the propagated multidimensional unit type data; and displaying one or more warning messages on the graphical user interface regarding the identified inconsistent units.

Fink et al (US 5,808,918) discloses a hierarchical biological modeling system and method that provides integrated levels of information synthesized from multiple sources. An executable model or a biological system is developed from information and structures based on the multiple sources. Once the model is created and balanced it can be used to provide insight into phenomena at the cellular, or subcellular level, as well as phenomena at the patient, organ and system levels. From this information clinical trials can be emulated, biologic targets for drug development can be identified and subcellular phenomena over time can be observed. The model provides an integrated view of a multi-variable biological system. Fink fails to teach or suggest a GUI having a plurality of objects representing pharmacokinetic and pharmacodynamic elements; connecting the objects according to instructions and displaying the connected objects; receiving units-specified data for the input and output of the connected objects; converting the connected objects and the units-specifying data into an internal format corresponding to the pharmacokinetic and pharmacodynamic elements represented by the connected objects; the converting step occurs substantially coincident with the displaying step; the internal format comprising statements having terms that have an associated multidimensional unit type corresponding to the received units-specifying data; propagating the multidimensional unit type data for each statement; identifying inconsistent units in the propagated multidimensional unit

type data; and displaying warning messages on the GUI regarding the identified inconsistent units.

Thalhammer-Reyero (US 5,930,154) discloses an integrated computer-based systems, methods, and graphical interface, providing an environment for development and deployment of visual models of complex systems organized in discrete time and space compartments, used for graphic information storage and retrieval, visual modeling and dynamic simulation of the complex systems. The system includes libraries of knowledge-based building-blocks that include sets of icons representing chemical processes, the pools of entities that participate in those processes, and the graphical description of those entities, encapsulating both information and mathematical models within the modular components, in the form of attributes or in the form of component icons, and a plurality of methods are associated with each of the icons. The models are built by linking each pool to one or several processes, and each process to one or several pools, resulting in complex networks of multidimensional pathways. A number of functions and graphical interfaces can be selected from the menus associated with each icon, to extract in various forms the information contained in the models built with the building blocks. Thalhammer-Reyero fails to teach that the building blocks or icons are representations of pharmacokinetic and/or pharmacodynamic elements; converting the connected objects and the units-specifying data into an internal

format corresponding to the pharmacokinetic and pharmacodynamic elements represented by the connected objects; a converting step that occurs substantially coincident with a displaying step; an internal format comprising statements having terms that have an associated multidimensional unit type corresponding to received units-specifying data; propagating multidimensional unit type data for each statement; identifying inconsistent units in the propagated multidimensional unit type data; and displaying warning messages on the GUI regarding the identified inconsistent units.

Grass et al (US 6,647,358 B2) discloses a pharmacokinetic-based design and selection tool (PK tool) and methods for predicting absorption of an administered compound of interest. Subsystems and individual components of the PK tool also can be used and adapted in a variety of disparate applications for predicting the fate of an administered compound. The PK tool and methods of the invention can be used to screen and design compound libraries, select and design drugs, as well as predict drug efficacy in mammals from in vitro and/or in vivo data of one or more compounds of interest. The PK tool and methods of the invention also find use in selecting, designing, and preparing drug compounds, and multi-compound drugs and drug formulations for preparation of medicaments for use in treating mammalian disorders. Grass fails to teach a GUI having connected objects that represent pharmacokinetic and/or pharmacodynamic elements; a converting step

that occurs substantially coincident with a displaying step; an internal format comprising statements having terms that have an associated multidimensional unit type corresponding to received units-specifying data; propagating multidimensional unit type data for each statement; identifying inconsistent units in the propagated multidimensional unit type data; and displaying warning messages on the GUI regarding the identified inconsistent units.

Conclusion

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

4. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to X L Bautista whose telephone number is (703) 305-3921. The examiner can normally be reached on Monday-Thursday (8:00-18:00), Fridays Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John W Cabeca can be reached on (703) 308-3116. The

fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

6. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

X L Bautista
Patent Examiner
Art Unit 2173

JOHN CABECA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2100

xlb
March 17, 2004